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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,990	07/14/2003	Scott Cunningham	2850	5967
50855	7590	12/20/2005	EXAMINER	
UNITED STATES SURGICAL, A DIVISION OF TYCO HEALTHCARE GROUP LP 150 GLOVER AVENUE NORWALK, CT 06856				POUS, NATALIE R
ART UNIT		PAPER NUMBER		
				3731

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/618,990	CUNNINGHAM ET AL.
	Examiner Natalie Pous	Art Unit 3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 July 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-15 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-15 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 14 July 2003 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>11/20/03</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input checked="" type="checkbox"/> Other: <u>10/16/03</u> .

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: (12) referring to elongated needle body. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 8, 9, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (US 5797961) in view of Smith (US 4799484).

Smith et al. (US 5797961) teach a surgical needle comprising the following features:

- An elongated body defining a longitudinal y-axis (5)
- A central shaft portion (40)
- A first suture end portion for attachment to a suture (205)
- A second needled end for penetrating tissue (50)
- The needled portion having three sides (560, 570)
- The needled portion having three cutting edges (564, 565, 600)
- Terminating in a needle point (30)
- Pair of planar surfaces (580, 590) arranged in oblique relation
- A distal shaft transition portion (40) defining a cross section of general triangular character (Column 3, proximate lines 4-8) interconnected by rounded surfaces (Fig. 6)
- At least one of the three sides is substantially planar (560)

Smith et al. (US 5797961) fails to disclose wherein the needle comprises an enlarged transition portion adjacent to central shaft portion where the x-dimension (height) of this portion larger than that of shaft. Smith (US 4799484) teaches a surgical needle with an enlarged (x1) transition portion (12) adjacent to the central shaft portion (16), wherein the x-dimension (height) of this portion (x1) is larger than that of the shaft portion (x2) in order to provide smoothly varying strength and performance characteristics. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the surgical needle of Smith (US 5797961) with an enlarged transition portion adjacent to the central shaft where the x-dimension (height) of this portion is larger than that of the shaft as taught by Smith (US 4799484) in order to provide smoothly varying strength and performance characteristics to the needle.

4. Claims 1, 3, 4, 7, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong (US 5030228) in view of Smith (US 4799484).

Wong et al. teach a surgical needle comprising the following features:

- An elongated body defining a longitudinal y-axis (10)
- A central shaft portion (25)
- A first suture end portion for attachment to a suture (30)
- A second needled end for penetrating tissue (11)
- The needled portion having three sides (12, 18, 20)
- The needled portion having three cutting edges (12a, 12b, 12c)

- Terminating in a needle point (P)
- Pair of planar surfaces (14, 22) arranged in oblique relation
- At least one of the three sides is substantially planar (12)
- Two of the cutting edges intersect at the needle point (P) and define an angle of about 22° to about 25° (Column 3, proximate lines 47-48)

Wong fails to disclose wherein:

- The needle comprises an enlarged transition portion adjacent to central shaft portion where the x-dimension (height) of this portion larger than that of shaft.
- the enlarged transition portion defines a z-dimension (width) greater than a corresponding z-dimension of the central shaft portion

Smith teaches a surgical needle with an enlarged (x1) transition portion (12) adjacent to the central shaft portion (16), wherein the x-dimension (height) of this portion (x1) is larger than that of the shaft portion (x2) in order to provide smoothly varying strength and performance characteristics. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the surgical needle of Wong with a an enlarged transition portion adjacent to the central shaft where the x-dimension (height) of this portion is larger than that of the shaft in order to provide smoothly varying strength and performance characteristics to the needle.

5. Claims 1, 2, 5, 6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen (US 5403344) in view of Smith (US 4799484).

Allen teaches a surgical needle comprising the following features:

- An elongated body defining a longitudinal y-axis (10)
- A central shaft portion (12)
- A first suture end portion for attachment to a suture (22)
- A second needled end for penetrating tissue (14)
- The needled portion having three sides (24)
- The needled portion having three cutting edges (20)
- Terminating in a needle point (18)
- Pair of planar surfaces (25, 26) arranged in oblique relation
- each of the three sides (24) include the planar surface portions (25, 26) arranged in oblique relation
- at least one of the sides (30) is substantially concave
- the planar surface portions of the one side intersect to define an included angle ranging from about 160° to about 175°, more specifically about 170°.

It is noted that according to the specification primary angle θ may be in the range of 30° – 120° but preferably 60°, and secondary angle α may range from 0° to 90°, but is preferably 30° (Column 3, proximate lines 39-43). Thus, in Fig. 7, using the stated preferred angles of $\theta= 60^\circ$, and $\alpha= 30^\circ$, α extends 15° past θ on either side of planar surface (25), creating an isosceles trapezoid defined by planar surfaces (25, 26, and base of ghost triangle 30 of

Fig. 8a), wherein the angle between the ghost base of triangle (30), and planar surface is 15°, and therefore the angle between oblique surfaces 26 and 25 is 165°. Further, in order for the included angle between oblique planar surfaces 25 and 26 to be about 170°, this requires the values of θ and α to change minimally and still be within the stated range of $\theta = 30^\circ - 120^\circ$ and $\alpha = 0^\circ$ to 90° . One possible configuration being $\theta = 60^\circ$, and $\alpha = 50^\circ$, α extends 10° past θ on either side planar surface (25), creating an isosceles trapezoid defined by planar surfaces (25, 26, and base of ghost triangle 30 of Fig. 8a), wherein the angle between the ghost base of triangle (30), and planar surface is 15°, and therefore the angle between oblique surfaces 26 and 25 is 170°.

Allen fails to disclose wherein the needle comprises an enlarged transition portion adjacent to central shaft portion where the x-dimension (height) of this portion larger than that of shaft. Smith teaches a surgical needle with an enlarged (x_1) transition portion (12) adjacent to the central shaft portion (16), wherein the x-dimension (height) of this portion (x_1) is larger than that of the shaft portion (x_2) in order to provide smoothly varying strength and performance characteristics. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the surgical needle of Wong with a an enlarged transition portion adjacent to the central shaft where the x-dimension (height) of this portion is larger than that of the shaft in order to provide smoothly varying strength and performance characteristics to the needle.

6. Claims 1, 8 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sardelis et al. (US 5403344) in view of Allen (US 5403344).

Sardelis et al. teach a surgical needle comprising the following features:

- An elongated body defining a longitudinal y-axis (50)
- A central shaft portion (60)
- A first suture end portion for attachment to a suture (80)
- A second needled end for penetrating tissue (70)
- The needled portion having three sides which intersect (Fig. 7)
- The needled portion having three intersecting cutting edges (90)
- Terminating in a needle point (70)
- The needle comprises an enlarged transition portion (line 7-7) adjacent to central shaft portion (60) where the x-dimension (height) of this portion larger than that of shaft (line 8-8).
- Wherein the central shaft portion (60) defines a distal shaft transition portion adjacent the needled portion (70), the distal shaft portion defining a cross-section of general triangular character (Fig. 8)
- The distal shaft portion includes three planar surfaces
- the needled end portion further defining an enlarged transition portion (Line 7-7) adjacent the central shaft section with an x-dimension (height) at least substantially equal to a corresponding x-dimension of the central shaft (line 8-8).

- the enlarged transition portion defines an x- dimension (Line 7-7) greater than a corresponding x-dimension (Line 8-8) of the central shaft portion (Fig. 6).
- the enlarged transition portion defines a z- dimension (width) at least substantially equal to a corresponding z-dimension of the central shaft (90, Fig. 5).
- the enlarged transition portion defines a z- dimension greater than a corresponding z-dimension of the central shaft portion (90, Fig. 5).

Sardelis fails to disclose wherein each side includes a pair of planar surfaces arranged in oblique relation. Allen teaches a surgical needle wherein a pair of planar surfaces (25, 26) are arranged in an oblique relation on each side in order to minimize the surface area of the needle in contact with the skin in order to provide improved penetration performance, less tissue trauma and distortion and a reduced wound opening area (Column 3, proximate lines 55-60). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the surgical needle of Sardelis with planar surfaces arranged in an oblique relation in order to minimize the surface area of the needle in contact with the skin in order to provide improved penetration performance, less tissue trauma and distortion and a reduced wound opening area.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Natalie Pous
11/18/05

Natalie Pous
Primary Art Unit 3731
Nov. 22.05